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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/473,904	12/28/1999	MARK S. CHEE	A-67493-2RFT	1618

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/473,904

Applicant(s)

CHEE ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19, 27, 28 and 36 is/are allowed.
- 6) ☒ Claim(s) 18-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2/03</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 9/2/03 has been entered.

2. The indicated allowability of claims 18-36 is withdrawn in view of the newly discovered reference(s) to WANG et al (US Patent 5,922,617). Rejections based on the newly cited reference(s) follow.

3. Claims 18-36 are currently pending and are being examined in this application.

Information Disclosure Statement

3. The information disclosure statement filed on 9/2/03 has been fully considered and entered into the application.

Drawings

4. The drawings filed on 12/26/99 have been considered as informal. Applicants are requested to file corrected drawings according to the PTO 948, mailed to applicants along the paper number 13.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 18-36 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential method steps and essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: The instant claims recite a method of determining the presence of one or more target analytes in a sample or samples, comprising: a) contacting the samples with a composition; b) determining the presence or absence of target analyte. However, the instant claims do not recite what is the relationship between the bioactive agents present on the microspheres and the target analytes; and how the presence or absence of the target analyte is determined. Applicants are requested to amend the claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 18, 20-24, 29-34 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,922,617 (WANG et al).

The instant claims briefly recite a method of determining the presence of one or more target analytes in one or more samples comprising: a) contacting said one or more samples with a composition comprising: I) a substrate with a surface comprising a plurality of assay locations,

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each assay location comprises an array location comprising a plurality of discrete sites; and ii) a population of microspheres comprising at least a first and second sub population of each comprising a bioactive agent; and b) determining the presence or absence of said target analyte.

Wang et al teach methods and apparatus for determining action between different components of the same or different compositions. The reference teaches that the method is for rapid screening of large number of components, where the variety of may be in either or both a bound first component or a soluble second component (refers to the 'target analyte' of the instant claims). The reference teaches that the devices have a solid support upon which the bound complements have been placed in predetermined registry in conjunction with the address encoders (addressable array) (refers to the composition of the instant claims). The reference method comprises: preparing the solid support for attachment of the first components; combining the first and second components to effect any interaction between the two components; and determining the presence of the interaction between the first and second components and particular sites (refers to instant claim steps and a) and b)) (i.e., see column 2). The reference teaches that the disclosed arrays may be used in a variety of ways for determining the presence of complementary nucleic acid in the sample. The reference teaches that the bound component will normally be an organic entity, which may be nucleic acid or protein (i.e., see column 3). The reference teaches that the array may be is used in determining the presence of complementary nucleic acid in the sample, in forensic medicine, detection of pathogens, both prokaryotic and eukaryotic, identification of the genes and mutations, such as genetic defects, antibiotic resistance genes, etc. (i.e., see column 7).

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The reference teaches that the arrays of bound components are one or more spokes or partial spokes on a disk (refers to the assay locations of the instant claims), the bound components may be in all or part of a single or plurality of channels preferred solid substrate is in circular form, which has plurality of circular grooves (i.e., see column 8). The reference teaches that the disk may be divided up into channels, which may be concentric, radial, eccentric etc., segments or other geometric form (i.e., see column 8). The reference teaches coding or tagging of the components bound to the solid support, preferably fluorescent dyes (refers to the optical signature of the instant claims). The reference figure 5 depicts the prepared arrays as individual segments. In the figure, segment 70 (refers to the assay locations of the instant claims) has a plurality of pits 72 (refers to the discrete sites of the instant claims) into which particles may be introduced. The reference teaches that each pit may or may not have same component. The reference teaches that the components are bound to the particles (beads) and are released into the tracks of the disk. The reference teaches that the component may be bound to magnetic beads which are usually be greater than 1 μ and less than about 100 μ (refers to the microspheres of the instant claims) (i.e., see column 5-6). Thus, the reference clearly anticipates the claimed invention.

Allowable Subject Matter

8. The following is a statement of reasons for the indication of allowable subject matter: The instant claimed method of determining the presence or absence of target analytes in the sample using the first substrate and the second substrate of the instant claims 19 and 36 is neither taught nor suggested by the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
03 May 2004


PADMASHRI PONNALURI
PRIMARY EXAMINER